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Proposed Maximum Residue Limit PMRL2015-47

Phorate

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Under the authority of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) has concluded that the registration of the new end-use product Thimet 20-G on potatoes, containing technical grade phorate, is acceptable. The specific uses approved in Canada are detailed on the label of Thimet 20-G, *Pest Control Products Act* Registration Number 29000.

While the evaluation of this phorate application indicated that the end-use product has value and the human health and environmental risks associated with the new uses are acceptable, the risks from exposure to total phorate residues from treated crops (other than potatoes), at the MRL levels established in exporting countries, exceed PMRA's level of concern. Therefore, MRLs are being proposed for all uses not registered in Canada at the limit of quantitation of the enforcement analytical method.

Before registering a pesticide for food use in Canada, the PMRA must determine the quantity of residues that are likely to remain in or on the food when the pesticide is used according to label directions and that such residues will not be a concern to human health. This quantity is then legally established as a maximum residue limit (MRL). An MRL applies to the identified raw agricultural food commodity as well as to any processed food product that contains it, except where separate MRLs are specified for the raw agricultural commodity and a processed product made from it.

Consultation on the proposed MRLs for phorate is being conducted via this document (see Next Steps, the last section of this document). A summary of the field trial data used to support the proposed MRLs can be found in Appendix I.

To comply with Canada's international trade obligations, consultation on the proposed MRLs is also being conducted internationally by notifying the World Trade Organization, as coordinated by the Canada's Notification Authority and Enquiry Point.

The proposed MRLs are as follows.

Table 1 Proposed Maximum Residue Limits for Phorate

Common Name	Residue Definition	MRL (ppm)[1]	Food Commodity
Phorate	*O,O*-diethyl *S*-[(ethylthio)methyl] phosphorodithioate and the metabolites phosphorodithioic acid, and *O,O*-diethyl *S*-(ethylthio)methyl ester, expressed in parent equivalents.	0.6	Potato flakes, potato granules
		0.2	Potatoes
		0.024	All food crops (other than those listed in this item)

[1] ppm = parts per million

International Situation and Trade Implications

MRLs may vary from one country to another for a number of reasons, including differences in pesticide use patterns and the locations of the crop field trials used to generate residue chemistry data.

Table 2 compares the MRLs proposed for phorate in Canada with corresponding American tolerances and Codex MRLs.[1] American tolerances are listed in the Electronic Code of Federal Regulations, 40 CFR Part 180, by pesticide. A listing of established Codex MRLs is available on the Codex Alimentarius Pesticide Residues in Food website, by pesticide or commodity.

Table 2 Comparison of Canadian MRLs, American Tolerances and Codex MRLs (where different)

Food Commodity	Canadian MRL (ppm)	American Tolerance (ppm)	Codex MRL (ppm)
Potato flakes	0.6	0.2	0.3
Potato granules	0.6		
Potatoes	0.2		
All food crops (other than those listed in this item)	0.024	Not Established[1]	Not Established[1]

[1] There are specific American tolerances and/or Codex MRLs established in various food crops, but none for "all food crops" as proposed by Canada.

Next Steps

The PMRA invites the public to submit written comments on the proposed MRLs for phorate up to 75 days from the date of publication of this document. Please forward your comments to Publications (see the contact information on the cover page of this document). The PMRA will consider all comments received before making a final decision on the proposed MRLs. Comments received will be addressed in a separate document linked to this PMRL. The established MRLs will be legally in effect as of the date that they are entered into the Maximum Residue Limit Database.

[1] The Codex Alimentarius Commission is an international organization under the auspices of the United Nations that develops international food standards, including MRLs.

Appendix I

Summary of Field Trial Data Used to Support the Proposed Maximum Residue Limits

No new field trial or processing residue data for phorate in potatoes were submitted to support the registration of the new end-use product Thimet 20-G. Previously reviewed residue data from field trials conducted in/on potatoes were reassessed in the framework of this petition. In addition, a processing study using treated potatoes was also reassessed to determine the potential for concentration of residues of phorate into processed commodities.

Maximum Residue Limits

The recommendation for maximum residue limits (MRLs) for phorate was based upon the previously submitted field trial data, and the guidance provided in the OECD MRL Calculator. MRLs to cover residues of phorate, phorate sulfoxide and phorate sulfone in/on potatoes and its processed commodities are proposed as shown in Table A1. Residues in processed commodities not listed in Table 1 are covered under the proposed MRLs for the raw agricultural commodities (RACs).

Table A1 Summary of Field Trial and Processing Data Used to Support MRLs

Commodity	Application Method/ Total Application Rate (g a.i./100 m row)[1]	Preharvest Interval (days)	Minimum Residues (ppm)[2, 3]	Maximum Residues (ppm)[2, 3]	Mean Experimental Processing Factor
Potatoes	In-furrow 0-7 days after planting/ 21-32	89-143	<0.05	0.27	Chips (0.19-fold); Granules/ flakes (2.2-fold)

[1] g a.i./100m row = grams of active ingredient per 100 metre row.
[2] Total phorate residues (phorate, phorate sulfoxide, phorate sulfone, phorate oxygen analog, phorate oxygen analog sulfoxide and phorate oxygen analog sulfone) determined as phorate oxygen analog sulfone.
[3] Total residues of phorate were greater than 0.2 ppm in only 1 of the 25 individual samples; furthermore 17 samples out of 25 contained no quantifiable residues.

Based on the dietary burden and residue data, finite residues of phorate are not anticipated in the meat, meat byproducts and milk of livestock.

Following the review of all available data, MRLs as proposed in Table 1 are recommended to cover residues of phorate, phorate sulfoxide and phorate sulfone only. Residues of phorate in these commodities at the proposed MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.